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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,602	12/31/2003	Daryll A. Emery	293.00010102	8548

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
08/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,602	EMERY ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-44,67-69,71-82 and 84-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-44, 67-69, 71-82 and 84-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/15/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

. DETAILED ACTION

Claims 34-44, 67-69, 71-82, and 84 –102 are pending in the application and were examined on their merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 34-44 and 67-69 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. US 6,682,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because the Instant claims are made obvious by claims 1-14 of '754.

Claims 1-14 of '754 teach a method for inducing immunity in a bird via implantation in ovo of a biocompatible implant providing for delayed and sustained release of an immunogen, wherein the implant is injected during the fourth quarter of incubation, during 15-28 days of incubation and day 17-19 of incubation of an egg and wherein the implant provides for sustained release of the immunogen for about 1-90 days or 1-60 days or 1-35 days post-hatching.

The claims of 1-14 do not specifically teach wherein the immunogen is a siderophore receptor such as enterochelin. However, the patent teaches that a preferred immunogen is enterochelin (see col. 10 line 45). Therefore, enterochelin is encompassed by the term 'immunogen'.

This rejection remains pending because Applicant has neither convincingly traversed this rejection, nor has Applicant furnished any terminal disclaimer in order to overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34, 37, 39-43, 67-69, 83-86, 89, 91-95 and 97-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al. (US 5,830,479) in view of Phelps et al. (US 5, 339,766) in view of Genovese et al. (1998) in light of Sharma et al. (US 4458630 A)*.

It is noted that new claims 85-86, 89, 91-95, 97-99 are directed toward substantially similar subject matter as claims 37, 39-43, 67 and 68 and are therefore rejected for the same reasoning as set forth previously for claims 37, 39-43, 67 and 68.

New claims 97-99 further limit claims 34, 69 and 84 respectively to wherein the method further comprises administration of an adjuvant. New claims 100 and 102 further limit claims 43 and 95 respectively to wherein the method further comprises wherein the second dose of the immunogen comprises a modified live vaccine.

Emery clearly teaches the advantageous use of adjuvants along with the siderophore receptor proteins, as well as the advantageous use of administering modified vaccines as the booster vaccination (see e.g., col. 2, lines 46-65 and col. 12 lines 7-31).

Therefore, one of ordinary skill in the art would have been motivated to administer an adjuvant with the siderophore receptor vaccine in order to facilitate immune stimulation in order to enhance the immune system's ability to produce

antibodies toward the vaccine. One of ordinary skill in the art would have been motivated to use a modified vaccine as a booster because these types of boosters were well-known to increase antibody titers as clearly taught by Emery. Therefore, one of ordinary skill in the art would have had a reasonable expectation that both of administration of an adjuvant, and administration of a modified vaccine for the booster would have successfully increased immunity to the vaccine.

Claims 34-44, 67-69, 71-82, and 84 –102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al. (US 5,830,479) in view of Phelps et al. (US 5, 339,766) and further in view of Evans et al. (US 6,500,438 B2) in view of Genovese et al. (1998) in light of Sharma et al. (US 4458630 A)*.

Claims 87, 88, 90 and 96 are directed toward substantially similar subject matter as claims 35, 36, 38 and 44 and are therefore rejected for the same reasoning as set forth previously for claims 35, 36, 38 and 44.

New claim 101 further limits claim 81 to wherein the method further comprises wherein the second dose of the immunogen comprises a modified live vaccine.

Emery clearly teaches the advantageous use of administering modified vaccines as the booster vaccination (see e.g., col. 2, lines 46-65 and col. 12 lines 7-31).

One of ordinary skill in the art would have been motivated to use a modified vaccine as a booster because these types of boosters were well-known to increase antibody titers as clearly taught by Emery. Therefore, one of ordinary skill in the art would have had a reasonable expectation that administration of a modified vaccine for the booster would have successfully increased immunity to the vaccine.

Applicant's arguments were fully considered, but were not found persuasive for the reasons set forth *infra*.

The Declaration of Inventor made of record on 5/15/07 of Daryll A Emery was fully considered. The *curriculum vitae* of Daryll A. Emery is duly noted. However, the Declaration is not found persuasive for reasons set forth *infra.*

Applicant's opening arguments, as well as the opening arguments in the Declaration are centered around the contention that the Examiner was incorrect in the analysis of the prior art with regard to maternal antibodies circulating in the avian eggs: "The Examiner assumes that the birds used in Example 3 of Emery et al. had maternal antibody" and contends that this amounts to "false assumptions and mis-characterization" on the part of the Examiner (p. 11, Remarks).

While Applicant has newly amended the claims to reflect that the egg contains the maternal antigens to the antibodies, *this was not the case in the previous claims*

which did not require the presence of maternal antibodies in the egg. 'Sufficiently reduced' is deemed to encompass no, or *zero antibodies.* Therefore, Applicant's repeated arguments concerning this topic (pp. 11-14) are without merit toward the previous rejection. Applicant's arguments are solely directed toward the fact that none of the references teaches that the inoculated eggs actually possessed circulating antibodies toward the vaccine which was used to inoculate the eggs. This is accepted, none of the references specifically teach wherein poultry is vaccinated, allowed to lay eggs, and then wherein the eggs were vaccinated with the same antigen as the mother poultry.

However, to reiterate, Emery specifically taught that the siderophore receptor proteins could have been used to challenge the immune systems of poultry and eggs alike (col. 11, lines 9-21). Therefore, in view of Emery et al. one of ordinary skill in the art would have recognized that the siderophore receptor protein could have been used in poultry and then subsequently in the poultry's fertilized eggs. One of ordinary skill in the art then would have been motivated to practice the protocols of egg inoculation which were well known in the art and keenly described by Phelps or Phelps in combination with Emery et al. One of ordinary skill in the art would have had a reasonable expectation that inoculation of the egg with a siderophore receptor protein would have had a reasonable expectation of success, even though maternal antibodies toward the siderophore receptor protein were present in the egg. Applicant has not convincingly demonstrated that an immune response *will not be* elicited in an egg which

has circulating maternal antibodies. Because Emery et al. was directed toward inoculation of an egg, one of ordinary skill in the art; for example, one who raises chickens for produce, would be motivated to inoculate *all* of the eggs of each successive generation of bird (or chicken or another avian species) according to well-known guidelines set forth in the prior art; i.e., Phelps et al. and Evans et al.. This flows naturally from the combined teachings of the prior art. Thus, once an egg has been inoculated it will more than likely have some maternal antibodies to the inoculated antigen. Regardless of the fact that the egg would or would not contain maternal antibodies toward the antigen, the ordinary artisan would have been motivated to further inoculate the eggs produced by this chicken which had been inoculated *in-ovo* because there would be a reasonable expectation that the inoculation would have afforded the unhatched bird some immunity to the antigen. Further, although the claims state that a maternal antibody must be present, there is no indication as to what amount the maternal antibodies must be present, and therefore, the claims could be directed toward as little as one antibody present in the egg. This is due to the fact that it is a guess as to when the vaccines should be given since there is no verifiable means given in the Instant specification in order to quantify the antibody titers of the fertilized eggs, or to predict the amount of maternal antibodies in a given avian egg. Therefore, the Instant specification gives preferred protocols of when to inoculate the eggs, assuming that the maternal antibody titers are 'sufficiently reduced' in the egg. However, this concept is deemed obvious because the prior art references clearly taught that the claimed times

for inoculation of an avian as well as the particular protocol parameters found in the claims were well-known.

> When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable varition..103 likely bars its patentability...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Thus, while Applicant alleges that the specific times of 'delayed' or 'sustained' introduction of the immunogen into the egg is preferred due to the avian's increased immune response *to a siderophore receptor*, the methods for introduction of an immunogen (vaccine) such as siderophore receptor proteins/porins into an avian species at the claimed times and under the claimed conditions were none the less known and rendered obvious in view of what was known in the art at the time the invention was made regarding poultry inoculation. A rejection under 35 U.S.C. ' 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17 U.S.P.Q. 2d 1417.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

August 1, 2007